COMMERCIAL
OPERATING INSTRUCTIONAL
MANUAL

MODEL EC4542G
TEMPORARY CARDIAC PACEMAKER

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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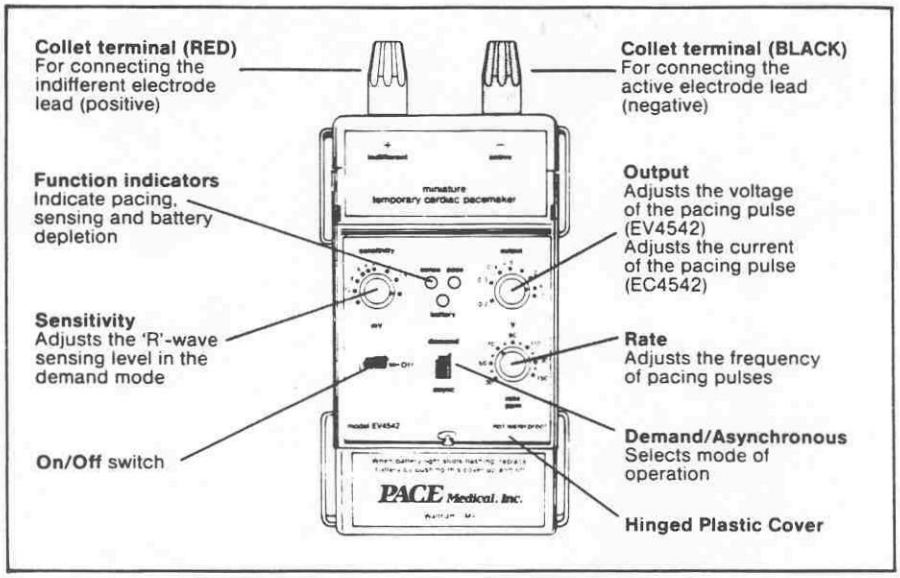
Collet terminal (RED)
For connecting the indifferent electrode lead (positive)
Collet terminal (BLACK)
For connecting the active electrode lead (negative)
Function indicators
Indicate pacing, sensing and battery depletion
Output
Adjusts the voltage of the pacing pulse (EV4542)
Adjusts the current of the pacing pulse (EC4542)
Sensitivity
Adjusts the 'R'-wave sensing level in the demand mode
Rate
Adjusts the frequency of pacing pulses
On/Off switch
Demand/Asynchronous
Selects mode of operation
Hinged Plastic Cover
PACE Medical, Inc.

Key to MINIATURE Pacemaker Controls and Features

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1. System Familiarization

1.1 Introduction

The Pace Medical Model EC4542G MINIATURE Temporary Pacemaker offers short-term pacing support for the patient with myocardial infarction or temporary heart block. The letter "C" in the Model number designates the unit as a constant current pacemaker.

In designing these pacemakers, the emphasis has been on producing a rugged, battery-powered pacemaker that is small and light enough to be comfortably worn by a patient, yet possessing all the attributes of the reliable bedside units manufactured for years by our subsidiary, APC Medical, Ltd., in the United Kingdom.

The Model EC4542G operates in either the R-wave inhibited (demand) or asynchronous mode with rate continuously variable within the range of 50 - 150 ppm when the switch is moved from off to on.

The output and sensitivity control scales are expanded at the lower settings to facilitate approximate threshold measurement.

In the presence of an excessive level of electrical interference (EMI), the pacemaker will automatically switch from the demand mode to a temporary asynchronous pacing mode approximately 25% higher than the selected rate. Normal function is resumed when the level of interference is reduced below the level of detection or stops completely.

Should an electronic component failure occur in the unit, the maximum high asynchronous rate is limited to 200 ppm.

1.2 Parts supplied

MINIATURE Temporary Cardiac Pacemaker, Model EC4542G

One 9 volt Alkaline battery

Two straps — for arm or body attachment

Information manual

Extension cable

Carrying case

1.3 Specifications

NOTE: The Model EC4542G has a current calibrated output.

Mode of Operation	R-wave inhibited or asynchronous
Current output (continuously variable) Accuracy +/- 0.05 mA or +/- 15%	0.5 — 20 mA
Pulse rate (continuously variable) Accuracy +/- 5%	50 — 150 ppm
Pulse duration (fixed) Accuracy +/- 0.15 ms	1.8 ms
High rate protection	200 ppm
Interference rate	Selected pulse rate +25%
Inhibit sensitivity (cont. var.) Accuracy +/- 30%	Calibrated for +1.0 to +12mV
Refractory period (after a stimulus) Accuracy +/- 30 ms	330 ms
Refractory period (after a sensed event) Accuracy +/- 30 ms	150 ms
Dimensions	76 mm x 145 mm x 33 mm
Weight	280 g or 9.8 oz.
Operating Temperature	+5° - +55°C (+41° - +131°F)

1.4 Indications and Contraindications

The Model EC4542G MINIATURE Temporary Pacemaker may be used in any clinical situation in which the use of a temporary pacemaker on a patient provides therapeutic or diagnostic value, or serves a prophylactic purpose. Specifically, indications for temporary pacemakers include, but are not limited to, the following: intermittent or complete heart block associated with asystole or bradycardia, symptomatic sinus bradycardia, surgically induced heart block and heart block accompanying an acute myocardial infarction.

There are no known contraindications to the use of temporary cardiac pacing as a therapeutic or prophylactic modality. Nevertheless, certain relative contraindications may exist in any given patient. Among others, the application of asynchronous pacing in competition with an intrinsic rhythm may provoke arrhythmias in electrically unstable individuals.

2. Features and controls

2.1 Function indicators

The Light Emitting Diodes (LED) indicate pacing, sensing and when the battery should be replaced.

2.1.1 Pacing

This light flashes once for every pulse delivered by the pacemaker in either the demand or asynchronous mode.

2.1.2 Sensing

This light flashes once for every sensed spontaneous R-wave in the demand mode only.

2.1.3 Battery replacement

This light flashes simultaneously with the flashing of the Sense or Pace light to indicate good battery condition. As the battery nears depletion, the Battery light will become less visible. IN THIS CONDITION, THE UNIT WILL CONTINUE TO PACE NORMALLY, BUT THE BATTERY SHOULD BE REPLACED AS SOON AS POSSIBLE.

2.1.4 Interference

If the unit is in the presence of detected interference; i.e., a signal repeating more frequently than 6Hz, both the Sense and Pace lights will flash. The Sense light is flashing in response to the interference signal.

The Pace light is flashing to indicate continued pacing in an asynchronous mode at a 25% increase from the rate indicated by the rate setting.

Figure 1

2.2 Controls

All controls are located on the face of the pacemaker and are protected by a hinged transparent cover. Refer to Figure 2.

2.2.1 Sensitivity Control

Adjusts the R-wave sensing level. This control is continuously variable from +1.0 to +12 mV and **is ineffective when the demand/async switch is set to async.**

2.2.2 Output control

Adjusts the current of the pacing pulse over the calibrated range of 0.5 to 20 mA.

2.2.3 Rate control

Adjusts the frequency at which pacing pulses are generated over the continuously variable range of 50 to 150 ppm.

2.2.4 Demand/Asynchronous switch

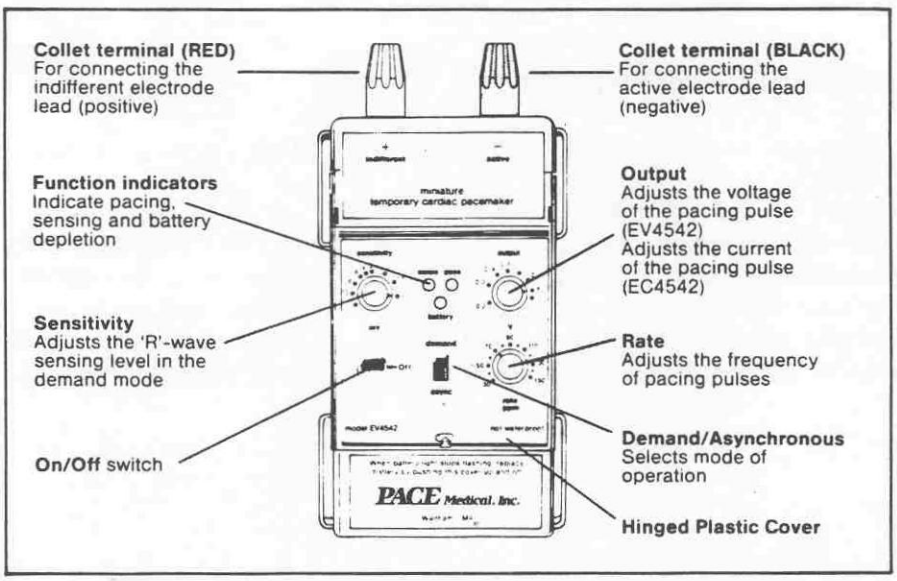
Selects the mode of operation.

2.2.5 On/off switch

Switches the pacemaker **on** and **off.**

2.3 Collet terminals

Accepts unipolar or bipolar leads ranging from 0.25 to 2 mm in diameter.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Key to MINIATURE Pacemaker Controls and Features
Figure 2

3. Operating Instructions

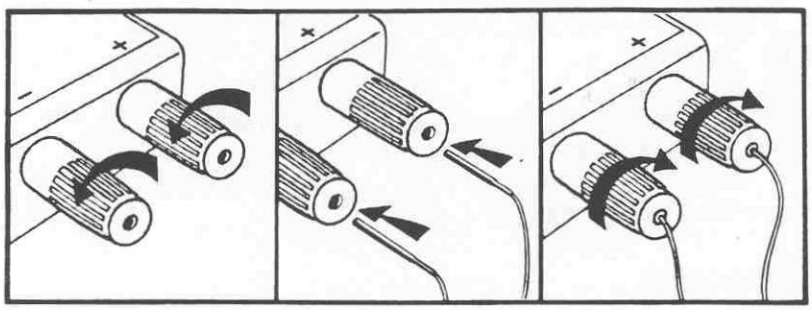
3.1 Lead Placement

When positioning the lead in the heart, it is recommended that the intracardiac ECG be monitored in order that the S-T segment elevation, indicating contact with the myocardium and impaction, can be noted.

3.2 Connecting the lead to the pacemaker

Switch the pacemaker **off.**

Connect the proximal electrode to the indifferent (+) red terminal and the distal electrode to the active (-) black terminal by the following method.



Connecting the Lead to the Pacemaker
Figure 3

Twist the terminal caps approximately three full turns counterclockwise, as illustrated, or until minimal resistance can be felt.

Push the lead electrodes into the end of the collet terminals and tighten by twisting the caps clockwise.

3.3 Determination of pacing threshold

a) Set the pacemaker **on/off** switch to **off (taking any special requirements of the patient into account).**
b) Set the **output** control to **6 mA.**
c) Set the pulse **rate** control to a value higher than the patient's spontaneous rate.
d) Select the desired pacing mode, **demand** or **async,** and set the **on/off** switch to **on.** The function indicator will show that pacing pulses are being generated at the preset rate.
e) Turn the **output** control counterclockwise until cardiac stimulation ceases and then slowly turn the control clockwise until pacing resumes. Note the stimulation threshold.

f) For reliable capture, increase the **output** control to a value three times the stimulation threshold. If necessary, readjust the pulse **rate** control to the minimum pacing rate required for the patient.

3.4 Pacemaker inhibition

To ensure reliable pacemaker inhibition, the R-wave sensing level should be preset as follows:

a) Ensure the pacemaker is switched **off (taking any special requirements of the patient into account).**
b) Set the **demand/async** switch to **demand.**
c) Set the **rate** control to a value below the patient's spontaneous rate.
d) Set the **output** control fully counterclockwise to **0.5 mA.**
e) Set the **sensitivity** control fully clockwise to **1.0 mV.**
f) Set the **on/off** switch to **on.**
g) Turn the **sensitivity** control counterclockwise until the sense light stops flashing. When this occurs, note the sensitivity setting.
h) For reliable inhibition, increase the sensitivity threefold; ie. if noted reading is **3 mV,** recommended setting is **1 mV.**
i) Increase the pacing **rate** control to the desired level and the **output** control to three times the pacing threshold.

4. Precautions

The controls on the Pace Medical Model EC4542G MINIATURE Temporary Cardiac Pacemaker should be operated only by qualified medical personnel.

Continuous ECG monitoring is necessary prior to pacing, during any pacing procedure, and in the immediate post-operative phase. Equipment for defibrillation, I.V. infusion, endotrachael intubation and oxygen administration must be immediately available.

The MINIATURE temporary cardiac pacemaker is protected against damage caused by defibrillatory discharges, but care should be exercised in the placing of defibrillator paddles well away from the pacing leads.

Great care should be exercised when using diathermy in association with any cardiac pacing system. Adequate monitoring must be used.

Line-powered monitoring equipment should be avoided when pacing, since even minute leakage occurs. If line-powered equipment is used, the manufacturer of the equipment, or person responsible for safety within your organization should be consulted on the safest method of connection.

The Model EC4542G pacemaker described in this information manual is not waterproof and it must not be immersed in cold sterilizing solutions. Additionally, it must not be sterilized using steam autoclaving or gamma irradiation techniques.

The Model EC4542G pacemaker is a life-support device. Section 6 of this manual describes the routine for battery maintenance. This is the only recommended user-serviceable item. In general, it is recommended that repair operations be performed by the specially trained technicians of Pace Medical, Inc.

When in routine use, it is recommended that calibration be checked at one year intervals.

CAUTION: The control knobs are individually calibrated. The pacemaker will need to be recalibrated if a knob is removed for any reason (see Section 8 for Warranty).

5. Equipment care

Hibiscrub/hibiclens, methylated spirits (alcohol), or a mild detergent applied with a soft cloth may be used to clean the Model EC4542G MINIATURE Temporary Cardiac Pacemaker. **A Model EC4542G must NOT be immersed in a cleaning solution.**

Ethylene oxide may be used to sterilize the MINIATURE. The temperature is typically 50°C (122°F) and the relative humidity should be 50 - 55%.

The battery should be removed before sterilization and a new battery installed afterwards.

The Model EC4542G MINIATURE pacemaker must not be sterilized by steam autoclaving or irradiation.

6. Alerts/troubleshooting

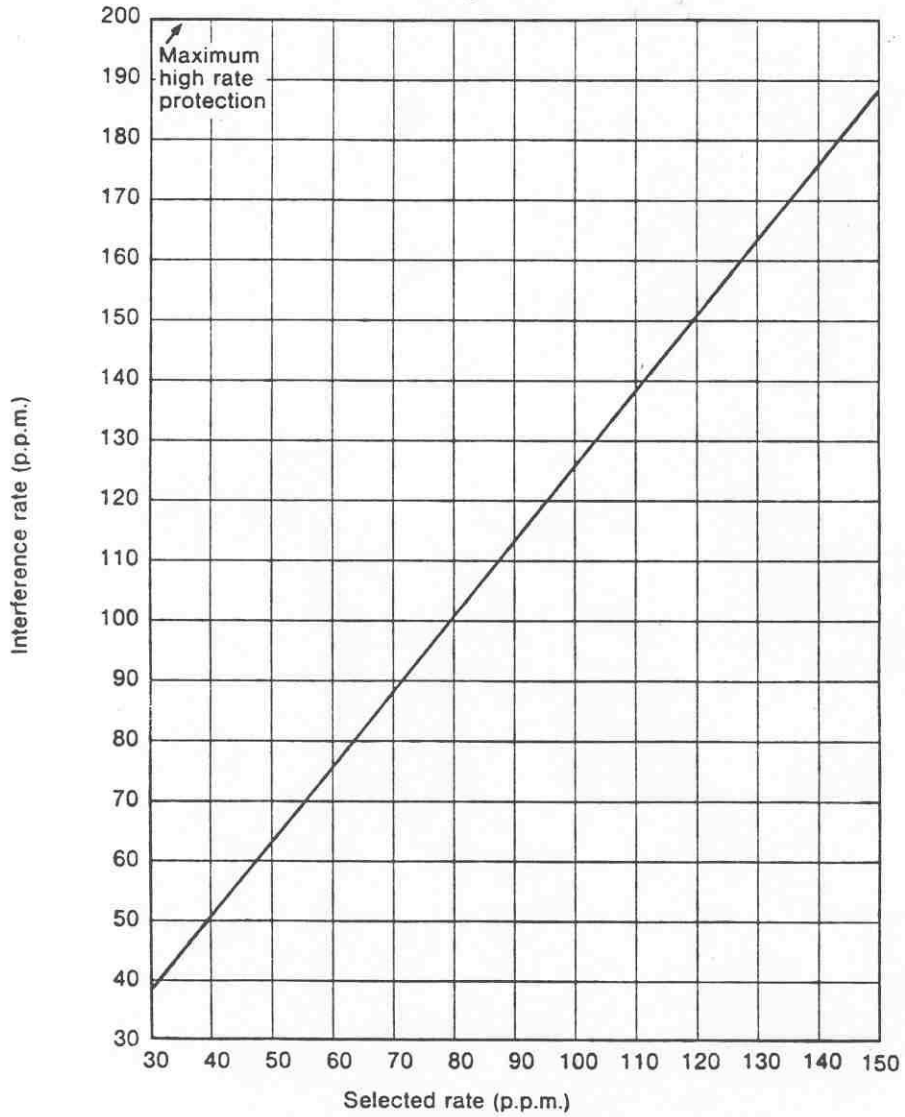
6.1 Interference

The Model EC4542G pacemaker is designed to reject interference frequencies outside of the R-wave bandpass. Detected signals which repeat with a frequency of 6Hz or greater will cause reversion to the interference mode.

When operating in the demand mode, an excessive level of electrical interference, for example, from diathermy or microwave ovens, will cause the pacemaker to switch automatically to asynchronous pacing at nominally 25% higher than that set on the **rate** control and both the sense and pace lights will flash. Normal function is resumed when the level of interference is sufficiently reduced.

The typical relationship between the selected pacing rate and the pacing rate when excessive electrical interference is present, is illustrated below in Figure 4.

Figure 4



6.2 High rate protection

Should an electronic component failure occur in the unit, the maximum high asynchronous rate is limited to 200 ppm.

6.3 Battery depletion and replacement

All MINIATURE pacemakers are designed to operate on 9V alkaline batteries. Spare batteries should be kept available at all times. It is recommended that a new battery be used with each patient.

Battery depletion is shown by a reduced visibility of the battery light during sensing or pacing. **When this occurs, the battery should be replaced immediately.**

The pacemaker will continue to function for 10 seconds while the battery is changed; replacement therefore can be carried out without disconnecting the pacemaker from the patient.

To change the battery, push the cover up over the battery compartment, as illustrated below, remove the battery and disengage the connector. Ensure that the contact terminals are clean. Fit the connector to the new battery, observing the correct polarity and replace the battery and cover. **As an additional safety precaution, the battery and contact terminals should be checked for corrosion at regular intervals.**

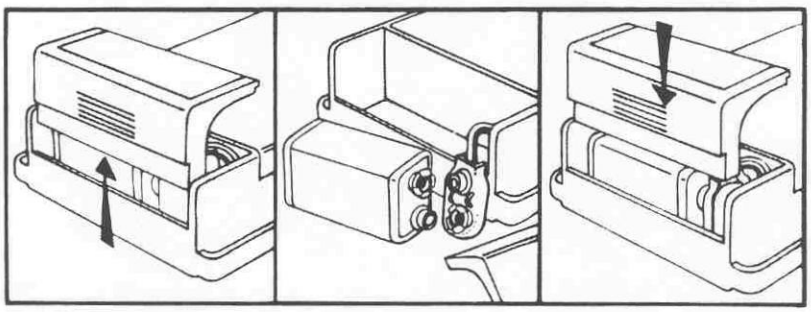


Figure 5

6.4 Miscellaneous

Additional minor device operating problems: 1) A failure to tighten the connector collets securely may lead to intermittent pacing and/or sensing; 2) Improperly set output and/or sensitivity controls may lead to the appearance of intermittent or complete failure to pace or sense; 3) Inappropriate asynchronous operation may be due entirely to the device being switched to **async** mode, or as noted earlier, interference from EMI. These normal and minor pacing complications should be considered prior to concluding that a more serious device malfunction is occurring. Repair, if needed, should be referred to a qualified biomedical technician or equivalent, or to Pace Medical, Inc.

7. Accessories/Parts

Parts supplied with a Model EC4542G MINIATURE are available from Pace Medical individually. No catalog number is required. A simple description of the accessory needed is usually adequate.

Similarly, certain parts of a MINIATURE itself, ex. battery compartment cover or clear control panel cover, may be ordered by mail or by calling the company at (617) 890-5656.

For the convenience of those who must utilize part numbers when ordering replacement items, the following is a list of the more commonly ordered replacement items and the Pace Medical part number.

Part Number	Description
83-003-000	Transparent face cover
01-003-000	Extension cable
03-001-001	Information manual
99-020-000	Arm strap
99-026-000	Body strap

8. Miscellaneous

8.1 Information

Further information about the MINIATURE Temporary Cardiac Pacemaker and other Pace Medical, Inc. products may be obtained from:

PACE MEDICAL, INC.
391 Totten Pond Road
Waltham, MA 02154

Tel: (617) 890-5656

8.2 Limited Warranty

Pace Medical, Inc., the Company, warrants the MINIATURE Temporary Cardiac Pacemaker to be free from defects in materials and workmanship for one year from the date of delivery when operated in accordance with the written Operating instructions which accompany the equipment.

This Warranty extends to the original purchaser of the equipment only and not any subsequent purchaser.

The Company's obligation under this Warranty shall be limited to repair or replacement of part or parts found to be defective during the Warranty period. All expendable items, such as Arm Straps, Extension Cables, and Batteries are not covered by this Warranty.

The equipment as sold may embody design or performance modifications not reflected in applicable literature. However, the Company warrants that such modifications will not reduce the design performance of the equipment.

Any repair or calibration to the circuitry during the period of the Warranty will invalidate the terms of the Warranty unless performed by Company personnel.

9. Storage

A MINIATURE pacemaker should be stored in its carrying case to protect it from accidental damage. The storage area should be clean and dry. The temperature of the storage area should be within the range of -25°C and +60°C (-13°F — +149°F).

Battery life of alkaline cells to be used with the Model EC4542G will be extended if they are maintained in normal refrigeration and rotated at least once annually.